

FOR TESTING PURPOSES ONLY:

This is NOT a real emergency

Marburg hemorrhagic fever has been reported in your neighborhood. Not everyone in your neighborhood will be affected by this case of Marburg hemorrhagic fever.

The Food and Drug Administration is working with the Centers for Disease Control and Prevention and other federal, state, and local agencies and health departments to provide you accurate information about this emergency. We will provide you with additional information as it becomes available.

Below is some information that can help you know if you or your family members should seek medical attention and about the antiviral medicine being used during this emergency to treat Marburg hemorrhagic fever exposure, which is called risanavir.

How do I know if I need treatment?

- Listen to official public health announcements on TV, radio, or the Internet for information about who should be checked by a health care professional.
- If you came in contact with someone with Marburg hemorrhagic fever, you should get checked out immediately by a health care professional even if you do not feel ill.
- Contact a health care professional or go to an emergency room right away if you think you have been exposed to Marburg hemorrhagic fever even if you don't feel ill. Officials may also set up emergency centers where people who may have been exposed can get checked.
- People who have symptoms may need immediate hospital care in addition to medicines, including risanavir.

How do I know if I need treatment with risanavir?

- Listen to official public health announcements on TV, radio, or the Internet for information about who should be checked by a health care professional.
- Marburg hemorrhagic fever is contagious. It can only be spread from one person to another by contact with body fluids from an infected person or through objects that have been contaminated with these fluids. Body fluids include blood, saliva, sweat, stool (feces), urine, tears and breast milk.
- The Marburg virus is not known to spread through the air.
- Contact your local health department, a health care professional or go to an emergency room right away if you think you have been exposed to someone with Marburg hemorrhagic fever or to contaminated objects even if you do not feel ill. Officials may also set up emergency centers where people who may have been exposed to the Marburg virus can get checked.
- People who have symptoms may need immediate hospital care in addition to risanavir.

What is risanavir?

- Risanavir is an antiviral medicine. The Food and Drug Administration (FDA) has authorized the emergency use of risanavir to treat Marburg hemorrhagic fever because

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there are no current FDA-approved medicines to treat the disease and people's lives are threatened by this emergency.

- Marburg hemorrhagic fever is a serious illness caused by the Marburg virus that can be spread from person to person. It can lead to death if untreated.
- Based on all the scientific evidence available to FDA, it is reasonable to believe that risanavir may be effective in treating Marburg hemorrhagic fever.
- The known and potential benefits of using risanavir to treat Marburg hemorrhagic fever in this emergency outweigh its known and potential risks.
- Risanavir will be given by health care professionals.
 - Risanavir comes in capsules.

What are the symptoms of exposure to Marburg hemorrhagic fever?

- Initial symptoms of Marburg hemorrhagic fever start suddenly and are frequently similar to the symptoms of a serious case of the flu. If not managed early, symptoms of Marburg hemorrhagic fever can get increasingly worse and be life-threatening.
 - Symptoms of Marburg hemorrhagic fever include fever, chills, headache, muscle aches and possibly a rash. Nausea and vomiting, abdominal pain, a sore throat, chest pain and diarrhea may then appear.
 - Early symptoms of exposure to Marburg hemorrhagic fever usually start to appear 5 to 10 days after exposure.
- Initial symptoms can develop into yellowing of the skin, severe bleeding, shock, and failure of organs throughout the body.
- Seek medical care immediately after exposure to the Marburg virus if you develop any of these symptoms.
- More information about the symptoms of exposure to Marburg hemorrhagic fever can be found at <https://www.cdc.gov/vhf/marburg/>

How do I reduce my risk of getting Marburg hemorrhagic fever?

- Avoid contact with contaminated objects and body fluids of a person infected with Marburg hemorrhagic fever.
 - Body fluids can include blood, saliva, sweat, stool (feces), urine, tears or breast milk. The Marburg virus is not known to spread through the air.
- Wash your hands often with warm water and soap for at least 20 seconds (about the time it takes to hum the Happy Birthday song twice) to reduce spreading the Marburg virus to other people.
- Avoid kissing others or sharing glasses or utensils.

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What are the possible side effects of taking risanavir?

- Because risanavir has been authorized for use only in this emergency, the possible side effects are not fully understood.
- However, risanavir is an antiviral medicine. Possible side effects associated with other antiviral medicines include fatigue, headache, weakness, loss of appetite, nausea and vomiting, insomnia, and anemia.
- Serious side effects from antiviral medicines are uncommon but they include yellow eyes or skin and light-colored stools, which may be signs of serious liver problems.
- Before taking risanavir, tell your healthcare professional if you have a pre-existing medical condition or are taking other medicines or supplements.
 - Pre-existing medical conditions include pregnancy, diabetes, or heart disease.
- Contact your health care professional if you have concerns about risanavir or if you experience serious side effects.

Why has the FDA authorized risanavir for use in this emergency?

- The FDA has authorized the emergency use of [DRUG NAME] to treat Marburg hemorrhagic fever because all of the following conditions are met:
 - Marburg hemorrhagic fever is a serious or life-threatening disease or condition to humans infected with the virus.
 - There is no adequate, approved, and available alternative to the emergency use of risanavir to treat the disease.
 - Federal government officials determined there is a significant potential for a public health emergency and that circumstances justify the emergency authorization of risanavir.

Have unapproved medicines been authorized for use in other public health emergencies?

- Unapproved medicines were authorized to be used in other public health threats, including to treat certain influenza (flu) viruses.

Where can I find more information?

For additional information about risanavir, visit or call:

- The Food and Drug Administration (FDA) Facts About Risanavir web page at www.fda.gov/risanavir
- 1-888-INFO FDA (1-888-463-6332)
- druginfo@fda.hhs.gov

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For more information about Marburg hemorrhagic fever, visit or call:

- The FDA Marburg Virus Response Update web page at www.fda.gov/marburg
- The Department of Health and Human Service website at <http://www.hhs.gov>
- The Centers for Disease Control and Prevention (CDC) website at <https://www.cdc.gov/vhf/marburg> or call: 1-800-CDC-INFO (1-800-232-4636)

For more information about Emergency Use Authorization, visit:

- Emergency Use Authorization web page:
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- MCM Emergency Use Authorities web page:
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-emergency-use-authorities>
- What are Medical Countermeasures?
<https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/what-are-medical-countermeasures>